REMARKS

I. Status of the claims and support for the amendments

Claims 1 and 5 are currently amended and new claims 18–20 are added.

Support for newly added claim 18 is found in claim 1 as originally filed. Support for newly added claims 19 and 20 is found in claims 8 and 11 as originally filed. Moreover, new claims 19 and 20 are analogous to claims 8 and 9. For this reason, Applicant believes there should be no objection to or rejection of claims 19 and 20.

Applicant explicitly reserves the right to pursue one or more divisional applications drawn to material, if any, cancelled by the current claim amendments.

II. Claim Objections

Claims 5, 8, and 11 are objected to as depending from rejected claims. Applicant responds as follows. In view of the current amendments to the claims and the remarks presented below, Applicant believes that all rejections of the claims have been overcome. Accordingly, the current objection is obviated and may now properly be withdrawn.

III. Rejection under 35 U.S.C. §112

A. Claim 1 is rejected under 35 U.S.C. §112, first paragraph as allegedly not being enabled by the Specification. Specifically, the rejection alleges that:

> the specification, while being enabling for a *method for aiding in the detection of CNS (central nervous system) damage in an individual, said CNS damage being caused by benign primary brain tumors, malignant primary brain tumors; by anoxia or ischemia, said method comprising the steps as set forth in claim 1,* does not reasonably provide enablement for *quantification of said damage using the method as set forth in claim 1.* The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims as set forth at pp. 4–17 ¶13–61 in the previous Office Action (paper No. 9, 3 April 2003).

(Emphasis in original). Applicant respectfully traverses.

With respect to claim 5 and new claims 18–20, Applicant notes that new claim 18 is identical to prior claim 1 (as pending prior to the instant response), except that the language "*and/or quantification*" is not present. Because the "and/or quantification" language was the primary reason for the rejection, under 35 U.S.C. §112, first paragraph, of previously pending claim 1, Applicant believes that claim 18 and its dependent claims 5, 19, and 20 are allowable.

With respect to claim 1 Applicant notes that this claim as currently amended is limited to analysis of CNS damage caused by "*anoxia or ischemia*". Applicant contends that the Specification provides sufficient disclosure to enable the proper correlation of a given tau level with the severity of the CNS damage caused by anoxia or ischemia. In Example 3 (pages 24 and 25 of the Specification), the extent of brain damage in patients was examined with computerized tomography (CT) scans of the brains of seven patients suffering from a brain attack (stroke). Figure 3 shows that there is a correlation between the size of the infarction as measured by the CT scan and the CSF-tau level (the figure shows a linear correlation between the level of CSF-tau and the size of the infarction). Thus, Example 3 clearly demonstrates that the level of CSF-tau corresponds with amount of damaged resulting from anoxia or ischemia (stroke). Therefore, it provides a quantitative measure of the CNS damage caused by the injury. Further, as currently amended, claim 1 now refers to this relationship wherein it recites that "an increase in tau level is an indication of an increase in the amount of CNS damage."

Given that the Specification clearly enables a method for quantifying the amount of CNS damages resulting from anoxia or ischemia, Applicant believes that, in view of the current amendment, the rejection of claim 1 (and therefore the objection of to claims 8 and 9) has been overcome and may now properly be withdrawn.

B. Claim 1 is rejected under 35 U.S.C. §112, second paragraph as allegedly being incomplete for omitting essential steps, such omission amounting to a gap between the steps. The Examiner

alleges that the "omitted steps are: how are the CSF tau levels determined in the patient and control patients." Applicant respectfully traverses.

The Examiner cites MPEP §2172.01 as authority supporting the current rejection. MPEP §2172.01 recites, in pertinent part:

> [a] claim which omits matter disclosed to be essential to the invention as described in the specification or in other statements of record may be rejected under 35 U.S.C. §112, first paragraph, as not enabling. *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). See also MPEP §2164.08(c). Such essential matter may include missing elements, steps or necessary structural cooperative relationships of elements described by the applicant(s) as necessary to practice the invention.

MPEP §2164.08(c), cited in § 2172.01, recites, in pertinent part, that:

> [l]imiting an applicant to the preferred materials in the absence of limiting prior art would not serve the constitutional purpose of promoting the progress in the useful arts. Therefore, an enablement rejection based on the grounds that a disclosed critical limitation is missing from a claim should be made only when the language of the specification makes it clear that the limitation is critical for the invention to function as intended. Broad language in the disclosure, including the abstract, omitting an allegedly critical feature, tends to rebut the argument of criticality.

As an initial observation applicant notes that both claim 1 and new claim 18 explicitly recite that the tau levels are to be determined in a cerebrospinal fluid (sample) obtained from the individual. Moreover, the claims recite that the CSF tau level from the subject individual is to be compared with a "range previously defined as characteristic for the CSF samples obtained from control healthy individuals... ." Thus, the claim clearly recites the source of the sample and how the sample is to be evaluated. Applicant believes that these are the required "steps".

Additionally, Applicant notes that MPEP §2172.01 indicates that the reasoning set out in the instant rejection may be used to support a rejection under 35 U.S.C. §112, *first* paragraph, not 35 U.S.C. §112, *second* paragraph. Accordingly, Applicant assumes that Examiner's citation of §112, second paragraph, was inadvertent. Response to the rejection will be made based on this assumption

and directed to a §112, first paragraph rejection. If this assumption is incorrect, clarification is respectfully requested.

Applicant further asserts that *how* the CSF-tau level is determined is not a critical element of the current claims. That is, the method used to determine the CSF-tau level is not critical to the efficacy of the instantly claimed method. Use of any suitable method for determining CSF-tau levels (several of which are well known to those of skill in the art) is appropriate for the operation of the instant claims. Furthermore, the current Specification teaches multiple means for determining CSF-tau levels (*see e.g.*, page 3, lines 22–27 and page 23, lines 6–8). The artisan of ordinary skill is well suited to select a method and then to use the method to determine the level of tau in patient suffering from CNS damage and compare this with the level in a control group of patients. The currently claimed invention does not contemplate nor require the use of any specific method for determining CSF-tau levels.

Applicant believes that an analogy is instructive; suppose for example that a claimed method required that a metal bar be fastened to a metal plate to serve as a "stop" (where the "stop" limited the rotation of a pivoting arm). Clearly, if the purpose of the metal bar is to act as a "stop", the means by which it is attached is not critical. Such a "stop" could be attached by bolting, by welding, by riveting, or by other suitable means. That is, the invention would function as claimed, regardless of how the metal bar is attached and so the method for attachment is not critical. Similarly, the benefit and function of the instantly claimed invention, does not depend on the means by which the CSF-tau level is determined. All that is required is that the CSF-tau level be determined.

Further, Applicant asserts that nowhere does the instant Specification teach or suggest that the use of a specific means for determining tau levels is essential to the function of the invention. Thus, in accordance with MPEP §§ 2164.08(c) and 2172.01, Applicant contends the current rejection is improper because, as §2164.08(c) states it would require limitation to a "preferred" means in "the

absence of limiting prior art". Furthermore, the "[b]road language in the [instant[disclosure, including the abstract" provides no indication that any particular method is required.

In view of these remarks, Applicant believes that this rejection has been overcome and may now properly be withdrawn.

IV. Conclusion

In view of the foregoing Amendments to the Claims and Remarks, Applicant believes that all rejections of and objections to the claims have been overcome and may now properly be withdrawn. Therefore, Applicant believes that the instant case is in condition for immediate allowance. Accordingly, Applicant respectfully requests favorable reconsideration of the application and the issuance of a Notice of Allowance therefor.

The Examiner is invited to contact the undersigned patent agent at (713) 787-1589 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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